



Final Regulation Agency Background Document

Agency name	Board of Dentistry, Department of Health Professions
Virginia Administrative Code (VAC) citation	18 VAC 60-20
Regulation title	Regulations Governing the Practice of Dentistry and Dental Hygiene
Action title	Requirements for administration of analgesia and local anesthesia by dental hygienists
Date this document prepared	12/14/07

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

The Board is amending regulations to comply with a statutory mandate as set forth in Chapter 858 of the 2006 Acts of the Assembly. In its regulatory action, the Board is establishing the education and examination required for a dental hygienist to demonstrate competency in the administration of local anesthesia and nitrous oxide under the direction of a licensed dentist, including a minimum of 8 didactic and clinical hours for administration of nitrous oxide and 36 hours for administration of both nitrous and local anesthesia.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

On December 7, 2007, the Board of Dentistry adopted final amendments to 18VAC 60-20-10 et seq., Regulations Governing the Practice of Dentistry and Dental Hygiene.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter numbers, if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Dentistry the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards

The general powers and duties of health regulatory boards shall be:

...

6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ [54.1-100](#) et seq.) and Chapter 25 (§ [54.1-2500](#) et seq.) of this title. ...

The Dental Practice Act (Chapter 27 of Title 54.1) was amended by Chapter 858 of the 2006 Acts of the Assembly (<http://leg1.state.va.us/cgi-bin/legp504.exe?061+ful+CHAP0858>) as follows: “A dentist may also authorize a dental hygienist under his direction to administer Schedule VI nitrous oxide and oxygen inhalation analgesia and, to persons 18 years of age or older, Schedule VI local anesthesia. In its regulations, the Board of Dentistry shall establish the education and training requirements for dental hygienists to administer such controlled substances under a dentist's direction.”

Therefore, the Board of Dentistry has a statutory mandate to establish education and training requirements for hygienists to administer.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

Chapter 858 of the 2006 Acts of the Assembly mandates the promulgation of regulations establishing the qualifications or credentials necessary for a dental hygienist to administer inhalation analgesia/nitrous oxide and local anesthesia. In the development of regulations, the Board looked at certification requirements in other states and considered a curriculum recommended by the VCU School of Dentistry. The didactic hours in an accredited program

coupled with a requirement for clinical experiences with patients and passage of an examination will ensure that a licensed hygienist will have the minimal competency to provide the expanded services with safety. In addition, the law and regulation require that administration must be under the dentist's direction (defined as meaning that "the dentist examines the patient and is present for observation, advice, and control over the performance of dental services").

Hygienists who are licensed by endorsement from other states can be qualified for administration, if their education and training was substantially equivalent to requirements of this chapter, or if not, by demonstrating years of experience in administration of nitrous or local anesthesia. Expansion of the scope of practice for dental hygienists should make these services more available to the citizens of the Commonwealth and should support appropriate dental care.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

The Board is mandated to promulgate regulations establishing the qualifications necessary for a dental hygienist to administer *Schedule VI nitrous oxide and oxygen inhalation analgesia and, to persons 18 years of age or older, Schedule VI local anesthesia*. Such qualifications include specific hours of didactic and clinical training, demonstration of clinical skills on patients, and testing of competency.

The law permits administration of nitrous oxide and local anesthesia by a dental hygienist if authorized by a dentist and only under his direction. "Direction" is already defined in regulations of the Board as "the dentist examines the patient and is present for observation, advice, and control over the performance of dental services," so regulations are specific about the level of supervision required for such administration.

In addition to establishing requirements for the education and training of dental hygienists, the Board has amended existing regulations for the administration of inhalation analgesia and the listing of non-delegable duties, consistent with the amended law. Current regulations for administration and monitoring by dentists are appropriately amended to allow hygienists qualified by education and training to also administer and monitor under the same provisions necessary to protect the health and safety of dental patients.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public.*

If there are no disadvantages to the public or the Commonwealth, please indicate.

- 1) The primary advantage of the proposed regulation to the public would be the expanded practice of dental hygienists who would be able to see more patients and provide additional services that require local anesthesia or administration of nitrous oxide. With the additional education and examination of such hygienists, the public could be assured that they possess credentialing indicating minimal competency. In addition, the law and regulation require that the supervising dentist be present and provide direction for the administration by a hygienist. The current requirements for monitoring and safety equipment are applicable regardless of which practitioner provides the administration. There should be no disadvantages to the public.

- 2) There are no specific advantages or disadvantages to the agency or the Commonwealth. Agencies of the Commonwealth that provide dental services may find it possible to expand those services to certain populations with the use of hygienists who are qualified to administer local anesthesia and nitrous.

- 3) There are no other issues or pertinent matters.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar’s office, please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
108	Current language requires that during the administration of anxiolysis, one member of the treatment team shall be in the operatory monitoring the patient at all times once the administration has begun, and that a dentist who utilizes anxiolysis shall ensure that there is continuous visual monitoring of the patient to determine the level of consciousness.	The amendment eliminates that requirement and substitutes with the following: “Once the administration of anxiolysis has begun, the dentist shall ensure that a person qualified in accordance with section 135 of this chapter is present with the patient at all times to determine the level of consciousness by continuous visual monitoring of the patient.”	The amendment was made in response to public comment. The commenter felt the language implies that it was necessary to have a third person to come in and monitor the patient’s level of consciousness. The treatment team consists of two persons – the dentist and a second person, who must be qualified in accordance with 135 in CPR, etc. It does not change but clarifies the intent of the regulation and the Board.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Proposed regulations for dental hygienists to administer nitrous oxide or local anesthesia were published in the Virginia Register of Regulations on August 6, 2007. Public comment was requested for a 60-day period ending October 5, 2007. A public hearing was held on September 7, 2007 to receive oral comment; none was presented. The following comment was received from one oral and maxillofacial surgeon: In section 108, there appears to be confusion about the intent of the regulation on the number of persons on the treatment team during the administration and monitoring of anxiolysis. There is also a need to define “monitoring” and “administration.”

Board response: With the concurrence and participation of the commenter, the Board amended section 108 for greater clarity. It considered the use of the two terms, “monitoring” and “administration” and determined that the comment should be considered during the periodic review it is presently conducting. The terms are used in numerous sections of the regulations, so a general review is required in order to determine whether definitions are needed and if so, the appropriate wording.

All changes made in this regulatory action

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
n/a	81	n/a	<p>Section 81. Sets out the requirements for administration local anesthesia and/or nitrous oxide by dental hygienists.</p> <p>Subsection A states the parameters for administration within the limitations of the law. It states that a dental hygienist who meets the qualifications set forth in this section and who is under the direction of a dentist may administer nitrous oxide/inhalation analgesia or, to patients 18 years of age or older, local anesthesia. It also clarifies that “local anesthesia” does not include topical Schedule VI medicinal agents which may be administered under general supervision pursuant to 18VAC60-20-220 B.</p> <p><i>The regulation is consistent with amendments to 54.1-2722 and 54.1-3408 of the Code of Virginia.</i></p> <p>Subsection B sets out the eligibility requirements for administration of only nitrous oxide/inhalation analgesia. Those requirements include:</p> <ol style="list-style-type: none"> 1. Successful completion of a didactic and clinical course leading to certification in administration of nitrous oxide offered by a dental or dental hygiene program accredited by the Commission on Dental Accreditation of the

		<p>American Dental Association, which includes a minimum of 8 didactic and clinical hours in the following topics:</p> <ol style="list-style-type: none"> a. Patient physical and psychological assessment; b. Medical history evaluation; c. Equipment and techniques used for administration of nitrous oxide; d. Neurophysiology of nitrous oxide administration; e. Pharmacology of nitrous oxide; f. Record keeping, medical and legal aspects of nitrous oxide; g. Adjunctive uses of nitrous oxide for dental patients; and h. Clinical experiences in administering nitrous oxide, including training with live patients. <p>and</p> <ol style="list-style-type: none"> 2. Successful completion of an examination with a minimum score of 75% in the administration of nitrous oxide/inhalation analgesia given by the accredited program. <p>Subsection C sets out the eligibility requirements for administration of <i>both local anesthesia and nitrous oxide/inhalation analgesia</i> to include:</p> <ol style="list-style-type: none"> 1. Successful completion of a didactic and clinical course leading to certification in administration of local anesthesia and nitrous oxide/inhalation analgesia which is offered by a dental or dental hygiene program accredited by the Commission on Dental Accreditation of the American Dental Association, which includes a minimum of 36 didactic and clinical hours in the following topics: <ol style="list-style-type: none"> a. Patient physical and psychological assessment; b. Medical history evaluation and record keeping; c. Neurophysiology of local anesthesia; d. Pharmacology of local anesthetics and vasoconstrictors; e. Anatomical considerations for local anesthesia; f. Techniques for maxillary infiltration and block anesthesia; g. Techniques for mandibular infiltration and block anesthesia; h. Local and systemic anesthetic complications; i. Management of medical emergencies; j. Clinical experiences in maxillary and mandibular infiltration and block injections; k. Pharmacology of nitrous oxide; l. Adjunctive uses of nitrous oxide for dental patients; and m. Clinical experiences in administering nitrous oxide and local anesthesia injections on patients. <p>and</p> <ol style="list-style-type: none"> 2. Successful completion of an examination with a minimum score of 75% in the administration of nitrous oxide/inhalation analgesia and local anesthesia given by the accredited program. <p><i>The course content is consistent with recommendations made by the Dean of the VCU School of Dentistry and the Director of the Dental Hygiene Program. It includes the</i></p>
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108	n/a	Sets out the general requirements for administration of anxiolysis or inhalation analgesia.	<p>Subsection B states the equipment requirements and provides that a dentist who utilizes anxiolysis or inhalation analgesia shall maintain the specified equipment in his office and be trained in its use. The amended regulation adds “or who directs the administration of inhalation analgesia by a dental hygienist.”</p> <p><i>Since a dental hygienist must be employed by and work under the direction of a dentist, it must be the responsibility of the dentist to ensure that the necessary safety equipment is available in the office for the administration of nitrous oxide.</i></p> <p>Subsection C sets out the monitoring requirements for anxiolysis or inhalation analgesia. <i>Amendments are</i></p>

			<i>adopted to distinguish between anxiolysis (which only dentists can administer) and inhalation analgesia (which both dentists and qualified hygienists can administer).</i>
190	n/a	Sets out the duties that cannot be delegated by a dentist to a dental hygienist.	With the change in the law, the administration of nitrous oxide or oxygen inhalation analgesia can no longer be a non-delegable duty. It may be delegated to a hygienist who meets the qualification set out in section 81.
220	n/a	Sets out the duties of a dental hygienist under direction with the dentist present or under general supervision,	Subsection A sets out the duties that can only be delegated to dental hygienists under direction with the dentist being present. To that list, the Board has added: "Administering nitrous oxide or local anesthesia by eligible dental hygienists qualified in accordance with the requirements of 18VAC60-20-81." <i>The requirement for administration of nitrous or local anesthesia under direction (with the dentist present and available) is consistent with the provisions of the Code.</i>

Regulatory flexibility analysis

Please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

According to the American Dental Hygienists’ Association, there are laws and/or regulations permitting dental hygienists to administer local anesthesia in 38 other states. To implement Chapter 858, the Board has reviewed educational and training requirements in other states – particularly states in this region of the country. At present, Kentucky, Tennessee, West Virginia and South Carolina have provisions similar to those in Virginia relating to administration of local anesthesia by hygienists.

In a review of requirements from other states, the Board found wide variation in the training and in the practice. The lowest number of hours of education was found in Kansas (12) with the highest number found in Louisiana (72). Following a recommendation of the Virginia Dental Association, the Board reviewed Kentucky regulations as a model for Virginia regulation because they appeared to be reasonable and balanced in the combination of didactic and clinical experiences and the passage of a qualifying examination.

In Kentucky, regulations require certification to administer infiltration anesthesia and nitrous oxide under the delegation and direct supervision of a dentist. To be eligible for a certificate granted by the Board, hygienists must complete 32 hours of course work in pharmacology, technique, evaluation, complications and contraindications from a dental or hygiene program

accredited by the ADA. To demonstrate clinical skills, they also have to complete at least 2 hours in clinical education in administration of nitrous oxide and demonstrate proficiency on at least 2 patients and a minimum of 12 hours in mastery of local anesthesia application with 3 injections in each of the sites. Finally, they have to pass a written examination administered after the coursework and clinical training.

The Board will recognize anesthesia education from other states if the instruction and course content requirements are equal to or greater than those in Virginia. Tennessee and South Carolina also issue local infiltration anesthesia certifications after successful completion of a board-approved certification course located in dental schools or community colleges; South Carolina only allows dental hygienist to monitor nitrous oxide rather than administer. North Carolina does not permit hygienists to administer nitrous or local anesthesia. If a hygienist is licensed by endorsement from another state and was qualified in that state by education and training that is not substantially equivalent, he may be qualified in Virginia by documenting experience in administration for 24 out of the past 48 months.

There was discussion about requiring hygienists to submit their education, training and examination credentials to the Board for approval, but that alternative was not accepted because there is no statutory authority for the Board to issue a certificate or to charge a fee for review of credentials. The dentist who employs the hygienist has the responsibility for assuring that he/she has met the requirements of the regulation and is legally administering the drugs.

The Board also considered a requirement for posting a certificate issued by the educational program in the operatory where the public is receiving the services. Since the certificate would not be issued by the Board, its posting would not necessarily convey evidence of minimal competency to the general public.

Other alternatives that were not included in the regulation were: 1) a requirement for passage of an examination offered by one of the regional testing companies (WREB has an examination but others do not yet offer one); 2) a requirement for continuing education (current CPR certification is required but there is no CE specified for administration of nitrous or local anesthesia); and 3) a requirement for dentists to teach the clinical portion of the course (hygiene instructors in dental hygiene programs may be well qualified to provide instruction in the clinical experiences).

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no impact of the regulatory action on the institution of the family and family stability.